

Amendment to the Claims:

The following listing of claims is intended to replace all previous claims.

Please amend claims 107, 124-126, 128, 130-137, 140-142, 149-154, 156-159 and 165-167 as shown.

Please cancel claims 143-148, 155, 160-164 and 168 without prejudice or disclaimer.

Please add new claim 169 as shown.

1-106. (canceled).

107. (currently amended) A method An assay for determining the optimal conditions for sterilizing a tissue containing that contains collagen without adversely affecting a predetermined biological characteristic or property of the tissue, thereof, said method comprising

- (i) irradiating the collagen under a pre-determined set of conditions effective to sterilize the said tissue;
- (ii) determining the turbidity of the said irradiated collagen; and
- (iii) repeating steps (i) and (ii) with a different pre-determined set of conditions until the said turbidity of the said irradiated collagen reaches a pre-determined acceptable level.

108-123. (canceled)

124. (currently amended) A method for reducing the level of active biological contaminants or pathogens in one or more tissues, said method comprising

contacting the one or more tissues tissue with a composition comprising propylene glycol and at least two other stabilizers selected from the group consisting of DMSO; mannitol; trehalose; sucrose; glycerol; inositol; sorbitol; xylose; glucose; ribose; mannose; fructose; erythrose; threose; idose; arabinose; lyxose; galactose; allose; altrose; gulose; and talose, and

irradiating the said one or more tissues with gamma radiation for a time effective to reduce the level of active biological contaminants or pathogens in the said one or more tissues.

125. (currently amended) A method for reducing the level of active biological contaminants or pathogens in one or more tissues, said method comprising

contacting the one or more tissues tissue with propylene glycol and

irradiating the said one or more tissues with gamma radiation,
wherein the total dose of gamma radiation is at least about 35 kGy for a time effective to reduce the
level of active biological contaminants or pathogens in said one or more tissues.

126. (currently amended) The method of claim 124 or 125 wherein the one or more tissues
tissue is hard tissue.

127. (previously presented) The method of claim 126 wherein the hard tissue is selected from the
group consisting of bone, demineralized bone matrix, joints, femurs, femoral heads and teeth.

128. (currently amended) The method of claim 124 or 125 wherein the one or more tissues
tissue is soft tissue.

129. (previously presented) The method of claim 128 wherein the soft tissue is selected from the
group consisting of collagen, connective tissue, epithelial tissue, adipose tissue, bone marrow, ligaments,
tendons, nerves, nerve cells, skin grafts, heart valves, portions of brain, cartilage, corneas, arteries and
veins.

130. (currently amended) The method of claim 124 or 125 wherein the said one or more tissues is
a combination of hard and soft tissue.

131. (currently amended) The method of Claim 124 or 125 wherein the said one or more tissues
is at a temperature below its freezing point during irradiation.

132. (currently amended) The method of claim 131 wherein the said one or more tissues is at a
temperature of about 0° C to about -196° C during irradiation.

133. (currently amended) The method of claim 131 wherein the said one or more tissues is at a
temperature of about -50° C to about -78° C during irradiation.

134. (currently amended) The method of claim 124 or 125 wherein the one or more tissues said tissue is maintained in an inert atmosphere during irradiation.

135. (currently amended) The method of Claim 124 or 125 wherein the one or more tissues said tissue is maintained under vacuum during irradiation.

136. (currently amended) The method according to claim 124 or 125 wherein the said irradiation is applied at a rate of at least about 0.3 kGy/hour to at least about 30.0 kGy/hour.

137. (currently amended) The method of claim 124 or 125 wherein the total dose of gamma irradiation is at least about 30 kGy.

138. (previously presented) The method of claim 124 or 125 wherein the total dose of gamma irradiation is at least about 45 kGy.

139. (previously presented) The method of claim 124 or 125 wherein the total dose of gamma irradiation is at least about 50 kGy.

140. (currently amended) The method of claim 124 or 125 wherein the concentration of the stabilizer or propylene glycol is at least about 20 mM to about 1 M.

141. (currently amended) The method of claim 124 or 125 wherein the concentration of the stabilizer or propylene glycol is at least about 100 mM to about 500 mM.

142. (currently amended) The method of claim 124 or 125 wherein the at least two other one of the stabilizers are selected from the group consisting of is DMSO, mannitol and trehalose.

143 – 148. (canceled)

149. (currently amended) The method of claim 124 or 125 further comprising adjusting or maintaining the pH of the said one or more tissues prior to irradiation.

150. (currently amended) The method of claim 124 or 125 further comprising reducing the residual solvent content of the one or more tissues tissue prior to irradiation.

151. (currently amended) The method of claim 150 wherein the said residual solvent is a non-aqueous solvent.

152. (currently amended) The method of claim 150 wherein the said residual solvent is an aqueous solvent.

153. (currently amended) The method of claim 150 wherein the said residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, addition of a second solvent, evaporation, chemical extraction and vitrification.

154. (currently amended) The method of claim 150 wherein the said residual solvent content is reduced to about about six (6) to about eight (8) percent.

155. (canceled)

156. (currently amended) The method of claim 124 or 125 further comprising contacting the said one or more tissues with at least one compound effective to increase penetration of the propylene glycol into the one or more tissues said tissue.

157. (currently amended) The method of claim 124 or 125 further comprising contacting the said one or more tissues with at least one sensitizer prior to irradiation.

158. (currently amended) The method of claim 157 wherein the at least one said sensitizer is selected from the group consisting of psoralen; 3-carboethoxy psoralens; inactines; angelicins; khellins; coumarins; brominated hematoporphyrin; phthalocyanines; purpurins; porphyrins; halogenated or metal atom-substituted derivatives of dihematoporphyrin esters; hematoporphyrin derivatives; benzoporphyrin derivatives; hydrodibenzoporphyrin dimaleimide; hydrodibenzoporphyrin; dicyano disulfone; tetracarbethoxy hydrodibenzoporphyrin; tetracarbethoxy hydrodibenzoporphyrin dipropionamide; doxorubicin; daunomycin; netropsin; BD peptide; S2

peptide; S-303 (ALE compound); hypericin; methylene blue; eosin; fluoresceins; flavins; merocyanine 540; bergapten; SE peptide; Cu²⁺ and Cu³⁺ and combinations thereof.

159. (currently amended) The method of claim 124 or 125 wherein the said one or more tissues contains at least one biological contaminant or pathogen selected from the group consisting of viruses, bacteria, yeasts, molds, fungi, parasites, prions, causative agents of transmissible spongiform encephalopathies and combinations thereof.

160 – 164. (canceled)

165. (currently amended) The method of claim 124 or 125 wherein the said one or more tissues are packaged prior to said irradiation.

166. (currently amended) A composition comprising one or more tissues prepared according to the method of claim 124 or 125.

167. (currently amended) The composition of claim 166 wherein the composition comprises propylene glycol and at least two ~~one or more~~ stabilizers selected from the group consisting of DMSO, mannitol and trehalose.

168. (canceled).

169. (new) A composition comprising one or more tissues prepared according to the method of claim 125.